

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

1-105. Canceled.

106. (Currently Amended) A composition comprising a polyester urethane and at least one filler material, wherein the composition is adapted to stimulate bone growth when the composition contacts or is positioned in the vicinity of a bone of a mammal, and wherein the composition is a product of a process comprising reacting a polyol, an isocyanate or isocyanate prepolymer, and water to generate carbon dioxide and produce in a final, cured state, a porous polyester urethane having an average pore size of from about 5 microns to about 500 microns, and a compressive strength of at least about 50 MPa.

107. (Original) The composition of claim 106, wherein the at least one filler material is present in an amount in the range of from about 0.01% to about 30% by weight

108. (Original) The composition of claim 106, wherein the at least one filler material is selected from the group consisting of calcium carbonate, bone, calcium phosphate, calcium pyrophosphate, hydroxyapatite, poly methyl methacrylate, glass-ionomer, poly ether ether ketone, calcium sulfate, and tricalcium phosphate.

109. (Original) The composition of claim 108, wherein the at least one filler material is bone that is selected from the group consisting of demineralized bone, allograft bone, and autogenous bone.

110. (Previously presented) The composition of claim 106, wherein the at least one filler material is beta tricalcium phosphate.

111. (Original) The composition of claim 106 wherein the polyester urethane is present in an amount in the range of from about 70% to about 99.99% by weight.

112.-117. Canceled.

118. (Original) The composition of claim 106, further comprising at least one substance selected from the group consisting of a radiotransparent substance and a radiopaque substance.

119. (Original) The composition of claim 118, wherein the at least one substance is at least one radiotransparent substance selected from the group consisting of gas, air, nitrogen gas, carbon dioxide, and oxygen gas.

120. (Original) The composition of claim 118, wherein the at least one substance is at least one radiotransparent substance selected from the group consisting of insoluble zirconium oxide, a radioactive tracer, a Barium Sulfate contrast media, a gadolinium contrast media, a water-soluble Iodinated contrast media, an oily Iodinated contrast media, and an implantable metal.

121. (Original) The composition of claim 106, further comprising at least one protein.

122. (Original) The composition of claim 106, wherein the composition is in a moldable state at room temperature for at least about 20 minutes after formulation.

123. (Original) The composition of claim 122 wherein the composition begins to cure at about room temperature at a time in the range of from about 20 minutes to about 30 minutes after formulation.

124. (Original) The composition of claim 106 wherein the composition attains a final, cured state within about 48 hours after formulation.

125. Canceled.

126. (Original) The composition of claim 124 wherein the composition in its final, cured state has a tensile strength of at least about 40 MPa.

127. (Original) The composition of claim 124 wherein the composition in its final, cured state has a Modulus of Elasticity of at least about 1,500 Mpa.

128. (Original) The composition of claim 124, wherein the final, cured composition further comprises at least one substance selected from the group consisting of a radiotransparent substance and a radiopaque substance, and wherein the presence of the at least one substance does not substantially affect the mechanical properties of the final, cured composition.

129. (Previously presented) The composition of claim 124, wherein the composition, upon attaining the final, cured state, does not comprise any reactive isocyanate.

130. (Previously presented) The composition of claim 106, wherein free filler material is absent of substantially absent from the final, cured composition.

131. (Previously presented) The composition of claim 124, wherein the mechanical properties of the composition are substantially unaffected when it is exposed to sterilization temperatures in an autoclave.

132. (Previously presented) The composition of claim 122, wherein the composition is adhesive and cohesive.

133. (Original) The composition of claim 106, wherein the composition is bactericidal.

134. (Original) The composition of claim 106, wherein the composition is bacterial static.

135.-325. Canceled.

326. (Original) A method of performing a medical procedure, comprising at least one step selected from the group consisting of:

applying a particular composition to at least one portion of a bone of a mammal;

positioning the particular composition in the vicinity of the bone;

dispensing the particular composition into an opening formed within or through at least one portion of the bone; and

positioning the particular composition between a first bone portion of the mammal and a second bone portion of the mammal for fusing the first bone portion to the second bone portion, wherein the particular composition:

stimulates bone growth; and

is a product of a process that comprises the steps of:

forming a first compound by mixing a naturally occurring polyol with a biocompatible, synthetic polyol;

mixing the first compound with isocyanate; and

permitting the first compound and the isocyanate to react to form a polyester urethane.

327. (Original) The method of claim 326 wherein the particular material does not substantially increase in temperature after being placed in at least the vicinity of at least one portion of a bone or a mammal.

328. (Original) The method of claim 327 wherein the temperature of the particular material does not substantially increase above about 45 °C after being placed in at least the vicinity of at least one portion of a bone of a mammal.

329. (Original) The method of claim 326 wherein the isocyanate is a cycloaliphatic isocyanate.

330. (Original) The method of claim 326, wherein the particular composition does not comprise any reactive isocyanate.

331. (Original) A method of performing a medical procedure, comprising at least one step selected from the group consisting of:

applying a particular composition to at least one portion of a bone of a mammal;

positioning the particular composition in the vicinity of the bone;

dispensing the particular composition into an opening formed within or through at least one portion of the bone; and

positioning the particular composition between the first bone portion of the mammal and a second bone portion of the mammal for fusing the first bone portion to the second bone portion, wherein the particular composition:

stimulates bone growth; and

is a product of a process that comprises the steps of:

mixing a naturally occurring polyol with isocyanate;  
permitting the naturally occurring polyol and the isocyanate to react to form a  
polyester urethane; and  
permitting water to be present in the composition.

332. (Original) The method of claim 331 wherein the particular material does not substantially increase in temperature after being placed in at least the vicinity of at least one portion of a bone of a mammal.

333. (Original) The method of claim 332 wherein the temperature of the particular material does not substantially increase above about 45 °C after being placed in at least the vicinity of at least one portion of a bone of a mammal.

334. (Original) The method of claim 331 wherein the isocyanate is a cycloaliphatic isocyanate.

335. (Original) The method of claim 331, wherein the particular composition does not comprise any reactive isocyanate.

336. (Original) A method of performing a medical procedure, comprising at least one step selected from the group consisting of:  
applying a particular composition to at least one portion of a bone of a mammal;  
positioning the particular composition in the vicinity of the bone;  
dispensing the particular composition into an opening formed within or through at least one portion of the bone; and  
positioning the particular composition between the first bone portion of the mammal and a second bone portion of the mammal for fusing the first bone portion to the second bone portion, wherein the particular composition:

stimulates bone growth; and  
is a product of a process that comprises the steps of:  
mixing a biocompatible, synthetic polyol with an isocyanate; and  
permitting the biocompatible, synthetic polyol and the isocyanate to react to form  
a polycster urethane.

337. (Original) The method of claim 336 wherein the particular material does not substantially increase in temperature after being placed in at least the vicinity of at least one portion of a bone of a mammal.

338. (Original) The method of claim 337 wherein the temperature of the particular material does not substantially increase above about 45 °C after being placed in at least the vicinity of at least one portion of a bone of a mammal.

339. (Original) The method of claim 336 wherein the isocyanate is a cycloaliphatic isocyanate.

340. (Original) The method of claim 336, wherein the particular composition does not comprise any reactive isocyanate.

341. (Original) A method of performing a medical procedure, comprising at least one step selected from the group consisting of:  
applying a particular composition to at least one portion of a bone of a mammal;  
positioning the particular composition in the vicinity of the bone;  
dispensing the particular composition into an opening formed within or through at least one portion of the bone; and

positioning the particular composition between the first bone portion of the mammal and a second bone portion of the mammal for fusing the first bone portion to the second bone portion, wherein the particular composition:

stimulates bone growth; and  
is a product of a process that comprises the steps of:  
forming an isocyanate prepolymer by mixing a  
biocompatible, synthetic polyol with isocyanate;  
mixing the isocyanate prepolymer with a naturally  
occurring polyol; and  
permitting the naturally occurring polyol and the isocyanate  
prepolymer to react to form a polyester urethane.

342. (Original) The method of claim 341 wherein the particular material does not substantially increase in temperature after being placed in at least the vicinity of at least one portion of a bone of a mammal.

343. (Original) The method of claim 342 wherein the temperature of the particular material does not substantially increase above about 45 C after being placed in at least the vicinity of at least one portion of a bone of a mammal.

344. (Original) The method of claim 341 wherein the isocyanate is a cycloaliphatic isocyanate.

345. (Original) The method of claim 341, wherein the isocyanate is a cycloaliphatic isocyanate.

346. (Original) A method of performing a medical procedure, comprising at least one step selected from the group consisting of:



applying a particular composition to at least one portion of a bone of a mammal;  
positioning the particular composition in the vicinity of the bone;  
dispensing the particular composition into an opening formed within or through at least one portion of the bone; and  
positioning the particular composition between a first bone portion of the mammal and a second bone portion of the mammal for fusing the first bone portion to the second bone portion, wherein the particular composition:  
stimulates bone growth; and  
is a product of a process that comprises the steps of:  
forming an isocyanate prepolymer by mixing isocyanate with a biocompatible, synthetic polyol;  
mixing the isocyanate prepolymer with a crosslinker or chain-extender; and  
permitting the isocyanate prepolymer and the crosslinker or chain-extender to react to form a polyester urethane.

347. (Original) The method of claim 346 wherein the particular material does not substantially increase in temperature after being placed in at least the vicinity of at least one portion of a bone of a mammal.

348. (Original) The method of claim 347 wherein the temperature of the particular material does not substantially increase above about 45 °C after being placed in at least the vicinity of at least one portion of a bone of a mammal.

349. (Original) The method of claim 346 wherein the isocyanate is a cycloaliphatic isocyanate.

350. (Original) The method of claim 346, wherein the solidified, particular composition does not comprise any reactive isocyanate.

351. (Original) A method of performing a medical procedure, comprising the steps of:  
forming a mold;  
dispensing a liquid, particular composition into the mold, wherein the particular composition solidifies within the mold;  
removing the solidified, particular composition from the mold; and  
positioning the solidified, particular composition on a bone of a mammal or within an opening formed through or in the bone, wherein:  
the positioned, particular composition stimulates bone growth; and  
the particular composition is a product of a process that comprises the steps of:  
forming a first compound by mixing a naturally occurring polyol with a biocompatible, synthetic polyol; and  
mixing the first compound with isocyanate.
352. (Original) The method of claim 351 wherein the particular material does not substantially increase in temperature after being positioned on a bone of a mammal or within an opening formed through or in the bone.
353. (Original) The method of claim 352 wherein the temperature of the particular material does not substantially increase above about 45 °C after being positioned on a bone of a mammal or within an opening formed through or in the bone.
354. (Original) The method of claim 351 wherein the isocyanate is a cycloaliphatic isocyanate.
355. (Original) The method of claim 351, wherein the solidified, particular composition does not comprise any reactive isocyanate.

356. (Original) A method of performing a medical procedure, comprising the steps of:  
forming a mold;  
dispensing a liquid, particular composition into the mold, wherein the particular composition solidifies within the mold;  
removing the solidified, particular composition from the mold; and  
positioning the solidified, particular composition on a bone of a mammal or within an opening formed through or in the bone, wherein:  
the positioned, particular composition stimulates bone growth; and  
the particular composition is a product of a process that comprises the steps of:  
mixing a naturally occurring polyol with isocyanate; and  
permitting water to be present in the composition.

357. (Original) The method of claim 356 wherein the particular material does not substantially increase in temperature after being positioned on a bone of a mammal or within an opening formed through or in the bone.

358. (Original) The method of claim 357 wherein the temperature of the particular material does not substantially increase above about 45 °C after being positioned on a bone of a mammal or within an opening formed through or in the bone.

359. (Original) The method of claim 356 wherein the isocyanate is a cycloaliphatic isocyanate.

360. (Original) The method of claim 356, wherein the solidified, particular composition does not comprise any reactive isocyanate.

361. (Original) A method of performing a medical procedure, comprising the steps of:  
forming a mold;

dispensing a liquid, particular composition into the mold, wherein the particular composition solidifies within the mold;

removing the solidified, particular composition from the mold; and

positioning the solidified, particular composition on a bone of a mammal or within an opening formed through or in the bone, wherein:

the positioned, particular composition stimulates bone growth;

and the particular composition is a product of a process that comprises the step of mixing a biocompatible, synthetic polyol with an isocyanate.

362. (Original) The method of claim 361 wherein the particular material does not substantially increase in temperature after being placed in at least the vicinity of at least one portion of a bone of a mammal.

363. (Original) The method of claim 362 wherein the temperature of the particular material does not substantially increase about 45 °C after being placed in at least the vicinity of at least one portion of a bone of a mammal.

364. (Original) The method of claim 361 wherein the isocyanate is a cycloaliphatic isocyanate.

365. (Original) The method of claim 361, wherein the solidified, particular composition does not comprise any reactive isocyanate.

366. (Original) A method of performing a medical procedure, comprising the steps of:  
forming a mold;  
dispensing a liquid, particular composition into the mold, wherein the particular composition solidifies within the mold;  
removing the solidified, particular composition from the mold; and

positioning the solidified, particular composition on a bone of a mammal or within an opening formed through or in the bone, wherein:  
the positioned, particular composition stimulates bone growth; and  
the particular composition is a product of a process that comprises the steps of:  
forming an isocyanate prepolymer by mixing a biocompatible, synthetic polyol with isocyanate; and  
mixing the isocyanate prepolymer with a naturally occurring polyol.

367. (Original) The method of claim 366 wherein the particular material does not substantially increase in temperature after being placed in at least the vicinity of at least one portion of a bone of a mammal.

368. (Original) The method of claim 367 wherein the temperature of the particular material does not substantially increase above about 45 °C after being placed in at least the vicinity of at least one portion of a bone of a mammal.

369. (Original) The method of claim 366 wherein the isocyanate is a cycloaliphatic isocyanate.

370. (Original) The method of claim 366, wherein the solidified, particular composition does not comprise any reactive isocyanate.

371. (Original) A method of performing a medical procedure, comprising the steps of:  
forming a mold;  
dispensing a liquid, particular composition into the mold, wherein the particular composition solidifies within the mold;  
removing the solidified, particular composition from the mold; and

positioning the solidified, particular composition on a bone of a mammal or within an opening formed through or in the bone, wherein:

the positioned, particular composition stimulates bone growth; and  
the particular composition is a product of a process that comprises the steps of:  
forming an isocyanate prepolymer by mixing isocyanate with a biocompatible, synthetic polyol; and  
mixing the isocyanate prepolymer with a crosslinker or chain-extender

372. (Original) The method of claim 371 wherein the particular material does not substantially increase in temperature after being placed in at least the vicinity of at least one portion of a bone of a mammal.

373. (Original) The method of claim 372 wherein the temperature of the particular material does not substantially increase above about 45 C after being placed in at least the vicinity of at least one portion of bone of a mammal.

374. (Original) The method of claim 371 wherein the isocyanate is a cycloaliphatic isocyanate.

375. (Original) The method of claim 371, wherein the solidified, particular composition does not comprise any reactive isocyanate.

376. (Original) A kit for promoting bone growth, comprising:  
a first container comprising a dispensing means and a first compound; and  
a second container comprising a dispensing means and a second compound.

377. (Original) The kit of claim 376, wherein the first compound comprises a naturally occurring polyol.

378. (Original) The kit of claim 377 wherein the second compound comprises an isocyanate prepolymer comprising isocyanate.

379. (Original) The kit of claim 376 wherein the first compound comprises a biocompatible, synthetic polyol.

380. (Original) The kit of claim 379 wherein the second compound comprises isocyanate.

381. (Original) The kit of claim 376 wherein the first compound comprises a polyol comprising a naturally occurring polyol and a biocompatible, synthetic polyol.

382. (Original) The kit of claim 381 wherein the second compound comprises isocyanate.

383. (Original) The kit of claim 376, wherein the first container is a syringe.

384. (Original) The kit of claim 383, wherein the second container is a syringe.

385. (Original) The kit of claim 376 wherein the first container and the second container are packaged in a moisture resistant package.

386. (New) The composition of claim 106, wherein the water is present in an amount ranging from about 0.1% to about 1% by weight of the composition.

387. (New) The composition of claim 106, wherein the polyol is a naturally-occurring polyol, a biocompatible, synthetic polyol or both.

388. (New) The composition of claim 106, wherein the at least one filler material is calcium carbonate.

389. (New) The composition of claim 106, wherein the isocyanate is an isocyanate prepolymer produced by reacting a diphenylmethane isocyanate mixture of 2,4 diphenylmethane isocyanate and 4,4-diphenylmethane isocyanate with a naturally occurring, difunctional castor-oil based polyol in a 4:1 equivalent ratio, and the process of producing the polyester urethane composition further comprises mixing calcium carbonate with the isocyanate prepolymer in an amount of about 72% by weight of the isocyanate prepolymer to form a paste, and adding to the paste in an amount of about 68% by weight of the isocyanate prepolymer, a quadrifunctional castor-oil based polyol crosslinker containing a tertiary amine catalyst in an amount of about 0.2 by weight percent of the crosslinker.

390. (New) The composition of claim 106, wherein the polyol is present in the isocyanate prepolymer in an amount ranging from about 10% to about 50% by weight of the isocyanate prepolymer, and the polyol is chosen from castor oil, safflower oil, lesquerella oil, chemically-modified vegetable oils, trans-esterified naturally-occurring oils, hydrogenated naturally-occurring oils, difunctional castor-oil based polyols, polycaprolactone polyols, polyester polyols, polyadipate polyols, and polyols derived from a synthetic acid.

391. (New) The composition of claim 106, wherein the composition has a Shore D Hardness suitable for a bone filler material.

392. (New) The composition of claim 106, wherein the composition has a Shore D Hardness similar to bone.



393. (New) The composition of claim 389, wherein the composition has a Shore D Hardness of about 72, a flexural strength of about 57 MPa, a strain at yield of about 5.8, and a modulus of about 2031 MPa.

394. (New) The composition of claim 389, wherein the composition has a Shore D Hardness of about 82, a flexural strength of about 85 MPa, a strain at yield of about 5.9, and a modulus of about 3193 MPa.

395. (New) The composition of claim 106, wherein the polyol is a naturally occurring polyol oil, and the isocyanate prepolymer is an isocyanate prepolymer formed by mixing a biocompatible, sythetic polyol with isocyanate.

396. (New) The composition of claim 106, further comprising reacting the isocyanate prepolymer with a chain extender or cross linker.